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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,588	07/20/2001	David C. Klein	14014.0342U2	3159

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EXAMINER	
FALK, ANNE MARIE	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 04/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 09/910,588	**Applicant(s)** KLEIN ET AL.
	Examiner Anne-Marie Falk, Ph.D.	**Art Unit** 1632

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 01 April 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *4* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1-3,5-8,10,11,15-17,19 and 20*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☒ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

Anne-Marie Falk

Anne-Marie Falk, Ph.D.
Primary Examiner
Art Unit: 1632

Continuation of 11. The request for reconsideration has been considered but does NOT place the application in condition for allowance because:

Exhibits A and C have been entered into the case and fully considered. Exhibit A, the 37 CFR 1.132 Declaration of Dr. Klein signed May 1, 2000, was considered previously in preparing the Office Action of 11/29/04 (see page 3 of the Office Action of 11/29/04). Exhibit C, the 37 CFR 1.132 Declaration of Dr. Klein signed December 31, 2002, is considered herein. Exhibit C is directed to Application Serial No. 09/374,742. However, prosecution in Application Serial No. 09/374,742 ended on 8/27/01. The 37 CFR 1.132 Declaration of Dr. Klein signed December 31, 2002 was not filed in parent case 09/374,742 and is not of record in that case.

At page 8, paragraph 3 of the response, Applicants argue that "it is improper for the Office to assert that the law requires the specification to teach how to use methods consistent with utilities recited in the specification but not claimed" (emphasis original). Applicants assert that the recitations noted in the specification regarding therapeutic benefit, limiting adverse effects of certain drugs, and improving the efficacy of certain drugs are not relevant to enablement of the present claims because the present claims do not recite those utilities. Contrary to Applicants' arguments, it is well established in our law that when a well-established utility is not readily apparent, it is the role of the specification to **assert** one or more utilities for the claimed invention. See MPEP 2164.07. In the instant case, the requisite **asserted utilities** are recited at page 15, lines 16-20 of the specification, which refers to prolonging the effectiveness of a drug and minimizing adverse reactions which result from acetylation of certain drugs, and at page 11, lines 15-16, which asserts that the present invention can be used to treat a disorder. At page 3, lines 21-22, the specification further asserts that the invention provides a method of treating a disorder caused by a decreased amount of serotonin. At page 8, lines 7-11, the specification discloses a number of disorders caused by a decreased amount of serotonin. At page 11, lines 20-21, the

specification asserts that depression can be treated by the claimed method. Contrary to Applicants' arguments, the specification must provide a utility for the claimed invention and further must teach how the use required by 35 U.S.C. 101 can be carried out.

MPEP § 2164.07 states the following:

> The requirement of 35 U.S.C. 112, first paragraph as to how to use the invention is different from the utility requirement of 35 U.S.C. 101. The requirement of 35 U.S.C. 101 is that some specific, substantial, and credible use be set forth for the invention. On the other hand, 35 U.S.C. 112, first paragraph requires an indication of **how the use (required by 35 U.S.C. 101) can be carried out**, i.e. how the invention can be used.
>
> If an applicant has disclosed a specific and substantial utility for an invention and provided a credible basis supporting that utility, that fact alone does not provide a basis for concluding that the claims comply with all the requirements of 35 U.S.C. 112, first paragraph. For example, if an applicant has claimed a process of treating a certain disease condition with a certain compound and provided a credible basis for asserting that the compound is useful in that regard, but to actually practice the invention as claimed a person skilled in the art would have to engage in an undue amount of experimentation, the claim may be defective under 35 U.S.C. 112, but not 35 U.S.C. 101. (emphasis added)

The instant specification fails to provide an enabling disclosure teaching how to use the claimed invention for therapy (or to prolong the effectiveness of a drug or to minimize adverse reactions which result from acetylation of certain drugs). The MPEP specifically addresses this situation. According to the MPEP § 2164.07, section II, titled WHEN UTILITY REQUIREMENT IS SATISFIED, "[i]n some instances, the use will be provided, but the skilled artisan will not know how to effect that use. In such a case, no rejection will be made under 35 U.S.C. 101, but a rejection will be made under 35 U.S.C. 112, first paragraph. As pointed out in *Mowry v. Whitney*, 81 U.S. (14 Wall.) 620 (1871), an invention may in fact have great utility, i.e., may be "a highly useful invention," but the specification may still fail to "enable any person skilled in the art or science" to use the invention. 81 U.S. (14 Wall.) at 644."

A teaching for producing the **claimed effect**, such as inhibiting melatonin production, in the absence of a teaching for achieving at least one of the **asserted utilities**, fails to meet the requirements of 35 U.S.C. 112, first paragraph. The Declaration of Exhibit C provides an *in vivo* example which demonstrates decreased pineal melatonin in isoproteronol-treated rats upon administration of BAT. However, neither the specification, the Declaration, nor the response shows that the observed inhibition of melatonin production (as recited in Claim 11) correlates with one of the asserted utilities. Thus, one of skill in the art would not know **how to use** the claimed method *in vivo* to achieve any one of the **asserted utilities.**

Therefore, the rejections are maintained for reasons of record.